UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

CADENCE PHARMACEUTICALS, INC. *et al.*, Plaintiffs, vs. FRESENIUS KABI USA, LLC, Defendant; _____ AND RELATED COUNTERCLAIMS; AND	Case No. 13cv139 DMS (MDD)
CADENCE PHARMACEUTICALS, INC. *et al.*, Plaintiffs, vs. SANDOZ, INC., Defendant; _____ AND RELATED COUNTERCLAIMS.	Case No. 13cv278 DMS (MDD) **ORDER GRANTING IN PART AND DENYING IN PART MOTION TO CONSOLIDATE**

Plaintiffs Cadence Pharmaceuticals, Inc. ("Cadence") and SCR Pharmatop ("Pharmatop") filed a motion to consolidate two patent infringement cases for all purposes. Defendant Sandoz, Inc. ("Sandoz;" case no. 13cv278) does not oppose consolidation. Defendant Fresenius Kabi USA ("Fresenius;" case no. 13cv139) filed an opposition. Plaintiffs filed a reply. For the reasons stated below, Plaintiffs' motion is granted in part and denied in part without prejudice.

This patent infringement action arises under the statutory scheme promulgated pursuant to the Drug Price Competition and Patent Term Restoration Act (the Hatch-Waxman Act). Cadence holds a New Drug Application ("NDA") for OFIRMEV. OFIRMEV is allegedly the first and only intravenous formulation of acetaminophen available in the United States, and has been approved by the Food and Drug Administration ("FDA"). Cadence is the United States licensee of U.S. Patent Nos. 6,028,222 ("the '222 patent") and 6,992,218 ("the '218 patent"). The patents claim novel formulations and methods of manufacturing aqueous acetaminophen solutions. Pharmatop is a French civil law partnership which owns the patents.

Fresenius submitted its own NDA under 21 U.S.C. § 355 and Sandoz submitted an Abbreviated New Drug Application ("ANDA") under 21 U.S.C. § 355(j). Both are seeking approval to engage in the commercial manufacture, use or sale of their generic acetaminophen injection products. Defendants' applications were each accompanied by a certification indicating that, in their opinion, the '222 and '218 patents are invalid, unenforceable and/or will not be infringed by the commercial manufacture, use, or sale of their products. *See* 21 U.S.C. § 355(b)(2)(A)(iv) (Fresenius); 21 U.S.C. § 355(j)(2)(A)(vii)(VI) (Sandoz). Based on these certifications, Plaintiffs filed the instant patent infringement actions.

On February 15, 2013, the Sandoz action was low-numbered to this Court because of the apparent similarities to the Fresenius action. On March 28, 2013, Plaintiffs moved to consolidate the actions under Federal Rule of Civil Procedure 42(a).

The America Invents Act ("AIA"), 35 U.S.C. § 299, limits consolidation of patent infringement cases for trial. However, the statute does not impose limitations on consolidation of pre-trial proceedings and, in any event, does not apply to infringement under 35 U.S.C. § 271(e)(2), which refers to NDA and ANDA applications described in 35 U.S.C. § 355(b)(2) & (j). 35 U.S.C. § 271(e)(2)(A). The AIA therefore does not preclude consolidation of the Fresenius and Sandoz actions.

Pursuant to Federal Rule of Civil Procedure 42(a),

> If actions before the court involve a common question of law or fact, the court may:
> (1) join for hearing or trial any or all matters at issue in the actions;
> (2) consolidate the actions; or
> (3) issue any other orders to avoid unnecessary cost or delay.

"The district court, in exercising its broad discretion to order consolidation of actions presenting a common issue of law or fact under Rule 42(a), weighs the saving of time and effort consolidation would produce against any inconvenience, delay, or expense that it would cause." *Huene v. U.S.*, 743 F.2d 703, 704 (9th Cir. 1984).

It is apparent on the face of the pleadings filed so far that the actions involve the same patents, similar products, and many of the same legal issues. Nevertheless, Fresenius opposes consolidation arguing it will be prejudiced by the delay which would ensue from consolidating the actions, and that the factual and legal issues in the two actions are not the same.

First, Fresenius contends the processing of its case, in this Court and the FDA approval proceedings, will be delayed if the cases are consolidated, and it will suffer prejudice from the delay. According to Fresenius, the FDA stay applicable to its NDA application is shorter than the stay applicable to Sandoz's ANDA application, enabling Fresenius's generic product to reach the market before Sandoz's, thus allowing Fresenius to reap greater profit from its research and development. Furthermore, the proceedings in this Court in the Fresenius action are a little further along than the Sandoz action. The Fresenius action was filed on January 17, 2013. An early neutral evaluation conference was held on April 5, 2013, and a case management order setting pre-trial and trial dates has issued. The Sandoz action was filed on February 4, 2013, and an early neutral evaluation conference has not yet been held. Finally, Fresenius intends to file an early summary judgment motion, which it claims will eliminate some of the hurdles to FDA approval of its product, and allow the Fresenius action to reach a resolution sooner than the Sandoz action.

Second, Fresenius posits the infringing products alleged in the two actions may be different, which it contends will lead to different non-infringement positions. Fresenius intends to argue its product does not infringe the '222 patent because it does not have a "buffer" ingredient. Fresenius contends this issue, which it claims is unique to its case, could be resolved on early summary judgment on undisputed facts and law. Fresenius also suggests that the process for making its product differs from Sandoz's process, potentially leading to different non-infringement positions with respect to the '218 patent. Fresenius does not argue that the patent invalidity arguments in the two cases will be different.

Consolidation of two patent infringement cases involving ANDA applications for generic drugs was ordered notwithstanding very similar arguments in *Cima Labs, Inc. v. Actavis Group HF*, 2007 WL 1672229 (D. N.J. Jun. 7, 2007). Given the substantial overlap in the factual and legal issues in the Fresenius and Sandoz actions, some level of coordination is warranted. However, the extent of differences in the non-infringement positions taken by Fresenius and Sandoz is unclear. Consolidation for all purposes is therefore not appropriate at this time. Nevertheless, Fresenius has presented no persuasive reason not to coordinate the actions for purposes of discovery and to proceed at the same pace.

For the foregoing reasons, it is ordered as follows:

1. Plaintiffs' motion is granted insofar as the cases shall be coordinated for purposes of discovery and all other pretrial proceedings. The motion is denied insofar as Plaintiffs seek consolidation for all purposes. The denial is without prejudice to making another motion for consolidation after Defendants' respective positions become more clearly defined.

2. On Friday, May 24, 2013 at 1:15 p.m., this Court will hold a joint telephonic case management conference in the Fresenius and Sandoz actions. The parties shall appear through counsel with authority to agree to case management dates.

IT IS SO ORDERED.

DATED: April 30, 2013

HON. DANA M. SABRAW
United States District Judge